## REMARKS

Entry of the foregoing amendments, reconsideration and reexamination of the subject application, as amended, pursuant to and consistent with 37 C.F.R. § 1.112, and in light of the remarks which follow, are respectfully requested.

### 1. Status of the Claims

Claims 1-29 are pending as correctly indicated in the Office Action Summary. By entry of this amendment, Claims 1-16, 18, 20-23, and 25-28 are pending.

Applicants have canceled claims 17, 19, 24, and 29 without prejudice or disclaimer thereto. Applicants have amended claims 1, 18, 20, and 25 without prejudice or disclaimer thereto. Amendments to the claims are supported by at least the claims as originally filed. No prohibited new matter is believed to have been introduce by entry of these amendments. Applicants reserve the right to file a divisional or continuation application on any subject matter which was canceled by way of this amendment.

### 2. Election of Group I

In complete response to the Restriction Requirement set forth in the Official Communication mailed May 23, 2002 (Paper No. 12), Applicants hereby elect ***with traverse*** the claims of Group I (Claims 1-19), which are drawn to a method for treating nerve disorders in a mammal.

Applicants traverse the election of the Group for at least the following reasons. Under M.P.E.P. § 803, a restriction is proper if the subject matter can be restricted into one of two or more claimed inventions, and these inventions are either independent (M.P.E.P. § 806.04) or distinct (M.P.E.P. § 806.05). However, the second element for a restriction requirement to be proper is that if the search and examination of an entire application can be made without serious burden, the examiner ***must*** examine it on the merits, even though it includes claims to independent and distinct inventions. Additionally, under M.P.E.P § 816, "[t]he particular reasons relied on by the examiner for holding that the inventions as claimed

are either independent or distinct should be concisely stated. A mere statement of conclusion is inadequate."

Applicants submit that a serious burden to examine both groups of claims has not been adduced. Moreover, Applicants assert that a search of the method of treating and the compositions used in the methods (*i.e.*, the claims of elected Group I) would result in an overlapping search of the claims of Group II (pharmaceutical compositions which are used in the methods of Group I, claims 20-29). Additionally, the added species requirement further limits any search burden (which has not been demonstrated to exist). Therefore, in view of at least the species election, the claims should be rejoined.

Accordingly, Applicants respectfully request reconsideration of the restriction, withdrawal of the election and rejoinder of the claims of Group II to those of Group I. Applicants respectfully request reconsideration of the restriction, especially in light of the additional species election (*i.e.*, the election of CDP-870), which greatly limits any purported burden on the Examiner.

3. **Election of Species**

As Applicants elected Group I, Applicants further elect, ***with traverse***, the TNF-α inhibitor species, CDP-870.

Applicants were further required to elect one of the following species of nerve disorders to be treated (1) a spinal disorder, (2) a nerve root injury, (3) a herniated disc, (4) sciatica, (5) a nucleus pulposus-induced nerve injury, and (6) spinal cord compression. Applicants elect (2) a nerve root injury ***with traverse.***

With regard to both species elections, Applicants again direct the Examiner's attention to M.P.E.P. § 803, which states: "If the search and examination of an entire application can be made without serious burden, the examiner ***must*** examine it on the merits, even though it includes claims to independent and distinct inventions." (Emphasis added) No basis as to why a search of these categories would be burdensome, let alone ***seriously*** burdensome, was set forth in the Office Action as required.

In addition to burden, the Office is also under a duty to demonstrate that the species are independent and/or distinct. M.P.E.P. § 806.04(b). No basis was provided as to why the members of the two sets of species are independent and/or distinct. The Applicants were only directed to elect a species from each category. *See* Office Action, Paper No. 12, page 3. Without meeting this duty, the species election has not been properly evinced. Additionally, no basis was provided why two sets of species elections is necessitated by the claims and art.

Additionally, under 37 C.F.R. § 1.141 and M.P.E.P. § 806.04(a), a reasonable number of species may still be claimed in one application. The Office provided no explanation explaining why more species could not be examined together (*e.g.*, examination of all monoclonal antibodies which are TNF-α inhibitors). *See* M.P.E.P. § 808.01(a).

Accordingly, as no distinction was presented and nor an explanation of why the numerosity of species was burdensome on the Examiner, Applicants respectfully request reconsideration or the species elections and their withdrawal.

## CONCLUSION

According, for at least all of the reasons set forth above, withdrawal of the requirement for restriction is requested and believed to be in order. Further and favorable consideration of all the claims of record on the merits is respectfully requested.

In the event that there are any questions relating to this Response to Restriction Requirement, or the application in general, it would be appreciated if the Examiner would telephone the undersigned attorney concerning such questions so that prosecution of this application may be expedited.

Respectfully submitted,

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**Attachment to Response to Restriction Requirement and Amendment**

**Marked-Up Claims 1, 18, 20, and 25**

1. (Amended) A method for inhibiting the action of TNF-α for treating nerve disorders in a subject by administering a TNF-α inhibitor comprising administering to said subject a therapeutically effective dosage of said TNF-α inhibitor wherein said TNF-α inhibitor is [CDP-571 (HUMICADE™), D2E7, or] CDP-870.

18. (Amended) The method of claim 1, wherein the TNF-α inhibitor is CDP-870 and is administered in a dosage of about 1 mg/kg to about 50 mg/kg body weight of said subject.

20. (Amended) A pharmaceutical composition for treating nerve disorders in a subject comprising a therapeutically effective amount of a TNF-α inhibitor wherein said TNF-α inhibitor is [CDP-571 (HUMICADE™), D2E7, or] CDP-870, and a pharmaceutically acceptable carrier, and wherein said pharmaceutical composition inhibits nerve injury when administered to said subject.

25. (Amended) The pharmaceutical composition of claim 20, wherein [said monoclonal antibody] the TNF-α inhibitor is CDP-870 in an amount of about 1.0 mg/kg to about 50 mg/kg body weight of said subject.